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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,849	12/14/2001	Jason P. McDevitt	03768/09630	7436

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EXAMINER	
LEWIS, KIM M	

ART UNIT	PAPER NUMBER
3761	9

DATE MAILED: 09/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/016,849	Applicant(s) MCDEVITT ET AL.	
	Examiner Kim M. Lewis	Art Unit 3761	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3-5, 7,8 and 9*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements filed 2/15/02, 3/22/02, 3/29/02, 9/10/02 and 10/30/02 have been received and made of record in the application file wrapper. Note the acknowledged PTO-1449 forms enclosed herewith.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As regards claim 1, the phrase "said wound site" in lines 8-9, lacks proper antecedent basis and should be rewritten as --the wound site-- at this instance, throughout the claim, as well as throughout the other claims in which the phrase is found. Also, "said wound" in line 10 should be rewritten as --the wound-- since the term "said" is generally reserved for component parts of the invention.

The remaining claims are necessarily rejected as containing the same indefinite language or as being dependent upon a rejected base claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. 1, 3, 4, 6, 7, 8, 19, 22-24, 26, 27, 29, 30 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,156,334 ("Meyer-Ingold et al.).

As regards claims 1, 3, 4, 6, 7, 19, 22-24, 26, 27, 29, 30, Meyer-Ingold et al. disclose wound coverings for removal of interfering factors from wound fluid. The invention is achieved by covalently bonding substances (enzymes, proteins, etc. (col. 2, lines 51-60)) that interact (*i.e.*, remove or eliminate) with interfering factors (proteases) present in wound exudates to a carrier material. Meyer-Ingold et al. further disclose the use of growth factors in combination with the interfering factors in order to improve the healing process of chronic wounds (col. 3, lines 26-34). Specifically, Meyer-Ingold et al. disclose that wound dressings (*e.g.*, dressing gauze, bandages, compresses, ***cotton-wool***, patches, foil, *etc.*) known in the prior art can be modified by covalently bonding the trapper molecules thereto and simultaneously applying would healing promoting substances such as growth factors (col. 9, line 57-col. 10, line 4) in the wound.

As to the method, although the steps are not explicitly stated, the process of making the disclosed wound dressing and then applying the wound dressing to a user reads on the steps of the instant invention. The claimed invention is therefore anticipated.

As regards claims 8 and 31, Meyer-Ingold et al. disclose cotton wool wound coverings. It is inherent that cotton wool is a blend of cotton and wool (*i.e.*, a woven blend).

As regards claims 15 and 20, Meyer-Ingold et al. disclose at col. 9, line 65-col. 10, line 4 that wound healing promoting substances, such as for example, growth factors can be applied into the wound, thereby being separate from the wound dressing.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 2, 4-7,10-14, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0064551 A1 ("Edwards et al.") in view of U.S. Patent No. 5,158,555 ("Porzilli").

As regards claim 1, Edwards et al. disclose a method for sequestering or inhibiting protease at a wound site that reads on the claimed invention. Edwards et al. specifically, disclose wound dressings of the formula x-a (x bonded to a), wherein x and a are selected from a long list of materials. Included in the list of materials are cotton cellulose formed as woven or nonwoven gauze and a dialdehyde[1], which is capable of removing a protease from a wound site once applied (abstract, paragraph 31, and page 3). This particular disclosure reads on steps (a) and (b) of the present claim.

Edwards et al. fail to teach step (c), selecting at least one protein from the group consisting of growth factors, cytokines, and chemokines for application to the wound site. However, Porzilli discloses a wound dressing comprising a protein containing a protein fibrous component and an epidermal growth factor (inherently a protein) in order to heal a wound quickly.

[1] U.S. Patent No. 4,335,017 discloses dialdehyde as a protein.

In view of Porzilli, it would have been obvious to one having ordinary skill in the art to modify the method disclosed in Edwards et al. with the additional step of adding a protein containing growth factor to the wound dressing in order to heal a wound quickly.

As regards claims 2 and 5, Edwards et al. fail to teach the protein containing fibrous component comprises silk fiber. However, Porzilli additionally teaches the wound dressing comprises a silk gauze layer inherently comprising silk fibers.

In view of Porzilli, it would have been obvious to one having ordinary skill in the art to modify Edwards et al. by constructing the carrier material from silk fibers since it has been well established that silk fibers, which contain silk proteins enhance skin health.

As regards claim 4, the protein-containing fibrous component comprises a protein containing fabric.

As regards claims 6 and 7, Edwards et al. disclose the use of cotton cellulose, of which cotton does not necessarily contain a protein.

As regards claim 10, note claims 2, 8 and 9 of Edwards et al.

As regards claims 11-14, Edwards et al. fail to specifically disclose that the protease comprises neutriphil elastase, gelatinase, and gelatinase B. However, the examiner contends that the type of protease located at the wound site depends on the location of the wound, the type of wound (i.e., acute or chronic), etc. The examiner further contends that the wound dressing of Edwards et al. is capable of inhibiting or sequestering different proteases at various wound sites, and that the selection of the

inhibitor or sequestrant to inhibitor or sequester the different types of proteases is within the level of ordinary skill in the art.

As regards claims 17 and 18,note the rejection of claim 1 above, which discusses the protein included as part of the dressing and the epidermal growth factors.

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer-Ingold et al. in view of U. S. Patent No. 5,856,245 ("Caldwell et al.").

As regards claim 9. Meyer-Ingold et al. disclose a wound covering constructed from a cotton-wool blend and fails to teach cotton–silk blend. However, Caldwell et al. disclose webs used in the manufacture of wound dressings, which comprise fibers of wool, cotton, silk and combinations thereof.

It would have been an obvious design choice to one having ordinary skill in the art to substitute the cotton-wool dressing for a cotton-silk dressing since Caldwell et al. teach it is known to construct dressings from these materials. The applicant should additionally note that the examiner contends that both blends perform equally well.

11. Claims 16 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer-Ingold et al.

As regards claims16 and 21, Meyer-Ingold et al. fail to disclose that the growth factor is in form of an ointment, lotion, solution or gel. Absent a critical teaching and/or a showing of unexpected results derived from the use of a growth factor in the form of an ointment, lotion, solution or gel, the examiner contends that the form of the growth

factor is an obvious design choice, which does not patentably distinguish applicant's invention.

12. Claims 24, 25, 28 and 32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 5,158,555 ("Porzilli").

As regards claim 24, Porzilli discloses the claimed invention. More specifically, Porzilli discloses a heal fast wound protection system in the form of a wound dressing comprising, a protein-containing fibrous component silk gauze (20) (col. 2, lines 45-54) and at least one growth factor, epidermal growth factor (col. 2, lines 55-63). ***The applicant should note that a protease found at the wound site may be attracted to and entrapped by the protein-containing fibrous component.***

Assuming arguendo that the applicant contends that gauze layer is not constructed from silk, the examiner contends that one having ordinary skill in the art would have been motivated to construct the gauze layer from silk since Porzilli defines it as being constructed from either cotton or silk.

As regards claim 25, it is inherent that the woven silk comprises silk fibers.

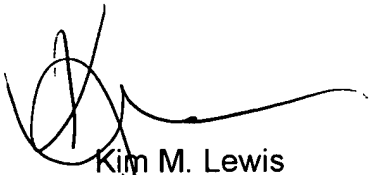
As regards claim 28, note the discussion above regarding silk gauze.

As regards claim 32, Porzilli discloses epidermal growth factors as discussed above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Mondays and Tuesdays from 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703.308.1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703.305.3590 for regular communications and 703.305.3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.



Kim M. Lewis
Primary Examiner
Art Unit 3761

kml
September 8, 2003